

REMARKS

The Office Action

Claims 5-42 are pending. Claims 13-16, 22-32, and 35-42 stand rejected for obviousness over Hubbell et al. (U.S. Patent No. 5,573,934; hereafter “Hubbell”). Claims 5-12, 17-21, 33, and 34 are allowed.

Rejections under 35 U.S.C. § 103

Independent claims 13, 15, 35, and 37 (from which the remaining rejected claims depend) stand rejected for obviousness over Hubbell. Applicants traverse this rejection.

To support an obviousness rejection, the Office must put forth a *prima facie* case that meets the legal standard for obviousness found in M.P.E.P. § 2142, which states:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant’s disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q. 2d 1438 (Fed. Cir. 1991) (emphasis added).

This standard has not been met in the present case, as Hubbell fails to teach or suggest the limitations of the instant claims and there is no motivation to modify the reference.

Each of claims 13, 35, and 37 recites a step for forming a precursor component via a conjugate addition reaction. Step (c) of claim 13 (from which claims 14 and 22-27 depend) recites:

(c) coupling a thiol, amine, or alkene group in said linker or incorporated into said pharmaceutically active compound to a water-soluble polymer or a water-swelling polymer comprising two or more conjugated unsaturated groups by a conjugate addition reaction to form a precursor component (emphasis added)

Step (b) of claim 35 (from which claim 36 depends) recites:

(b) coupling the thiol or amine in said linker or incorporated into said pharmaceutically active compound to a polymer comprising two or more conjugated unsaturated groups by a conjugate addition reaction to form a precursor component (emphasis added)

And step (b) of claim 37 (from which claims 38 and 39 depend) recites:

(b) coupling the thiol or amine in said linker or incorporated into said pharmaceutically active compound to at least a first polymer comprising two or more conjugated unsaturated groups by a conjugate addition reaction to form a precursor component (emphasis added)

As described in the specification on pages 54-66, a conjugate addition reaction involves the reaction of a nucleophile, i.e., a molecule capable of donating an electron pair (page 27), with a conjugated unsaturated group, i.e., a group with alternating single and multiple bonds (page 28). Nowhere does Hubbell teach or suggest such a reaction scheme.

As noted by the Office, Hubbell discloses a method for producing polymers by employing a free radical polymerization process. In characterizing Hubbell, the Office further states that:

Hydrophilic surfaces can be coated by applying a thin layer ... of a polymerizable solution such as PEG diacrylate containing appropriate amounts of dye and amine. (col. 14).

Therefore the reference disclose[s] making a biomaterial composition comprising attaching a pharmaceutical material to a molecule comprising a nucleophilic moiety.

This characterization is incorrect. It appears that Office is confusing the radical initiation by a dye and amine described in Hubbell with the conjugate addition reaction of claims 13, 35, and 37. As described in Hubbell, dye-sensitized polymerization occurs as follows: “After absorbing the laser light, the dye is excited to a triplet state. The triplet state reacts with a tertiary amine such as the triethanolamine, producing a free radical which initiates the polymerization reaction.” (col. 7, ll. 16-20) Thus, as described by Hubbell, the amine acts merely to produce a free radical, which is well understood in the art to be an unpaired electron. Applicants also emphasize that the free radical method of Hubbell requires light or heat to initiate (col. 3, ll. 43-45; col. 5, ll. 55-59; and col. 8, ll. 15-20). In addition, many examples of polymerization in Hubbell involve the reaction of an acrylate group with itself (e.g., col. 17-18, Example 3).

In contrast, a conjugate addition reaction, as recited in claims 13, 35, and 37 and described on pages 54-66, requires the reaction of a nucleophile having paired electrons directly with a conjugated unsaturated group. An example of this reaction is the addition of a thiol to an acrylate group (page 98, Example 2). Applicants note that the conjugate addition reaction occurs without the need for the addition of light or heat, unlike a free

radical process; that the nucleophile in the conjugate addition has paired electrons, unlike the unpaired electron of a radical process; and that a conjugate addition reaction cannot occur between two acrylate groups, unlike in a radical process, further distinguishing the invention of claims 13, 35, and 37 from the teachings of Hubbell. As Hubbell is directed solely to free radical polymerization, which is a distinct chemical process from conjugate addition reactions, Hubbell cannot teach or suggest the limitations of claims 13, 35, or 37.

Further to the above, the entire disclosure of Hubbell is directed to methods of producing polymers via free radical polymerization. Hubbell does not suggest anywhere that other methods of polymerization would be suitable or desirable. Thus, there is no motivation to modify Hubbell's approach to produce the method of claims 13, 35, and 37, since the Hubbell methods work and meet their stated goals, and the reference provides no indication that other approaches are feasible.

In conclusion, since Hubbell does not teach or suggest the limitations of claims 13, 35, or 37 and there is no motivation of record to modify Hubbell to produce the instantly claimed methods, the rejection of these claims for obviousness should be withdrawn.

The rejection of claim 15 (from which claims 16, 28-32, 41, and 42 depend) should also be withdrawn. Claim 15 is directed to a method of treating or preventing a disease by administering a composition that has an amide or ester bond that has a half life of between 1 hour and 1 year under specified conditions.

The Office is reminded that “[t]he initial burden is on the examiner to provide some suggestion of the desirability of doing what the inventor has done.”

(M.P.E.P. § 2142) In the present case, the Office failed to establish a *prima facie* case of obviousness for claim 15 because it did not provide any comments relating to this claim anywhere in the action. Applicants further note that Hubbell is silent with regard to the half life of any ester or amide bond, so it cannot teach or suggest the limitations of claim 15. There is therefore no evidence of record that Hubbell teaches or suggests the limitations of claim 15, and the rejection should be withdrawn. If the Office persists in this view, Applicants request that the Examiner provide detailed reasoning to support the rejection.

Information Disclosure Statement

The literature references cited in the Supplemental Information Disclosure Statement mailed on January 26, 2004 were lined through by the Office because the Office could not locate them. A telephone conference with the Examiner confirmed that the references are in the file wrapper for the parent case, U.S.S.N. 09/496,231. A replacement Form PTO 1449 listing these references has been enclosed herewith, and Applicants request that the Examiner initial this form and return it with the next Office action.

CONCLUSION

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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